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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/772,672	02/05/2004	Robert Edward Burrell	14072-012002	5559

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EXAMINER	
PAK, JOHN D	
ART UNIT	PAPER NUMBER
1616	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/22/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/772,672	BURRELL ET AL.	
	Examiner	Art Unit	
	JOHN PAK	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 December 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *90-113* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *90-113* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

This Office action is in response to applicant's arguments of 12/11/2006.

Claims 90-113 are pending in this application. Claims have not been amended since the previous examination of this application.

Applicant's election of Group I in the reply filed on 12/11/2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Accordingly, claims 90-113 will presently be examined to the extent that they read on the elected subject matter of record.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 90-113 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Burrell et al. (US 5,681,575) in view of Fan (WO 00/44414) for the reasons of record. See pages 7-10 of the Office action of 9/12/2006.

Applicant's arguments relative hereto have been given due consideration but they were deemed unpersuasive. Applicant takes a two-pronged approach in traversing this ground of rejection. First, applicant argues that the combined teaching of the prior art "does not enable one skilled in the art to make the subject matter covered by the claims." Second, applicant argues that the claimed invention provides "surprising"

properties and advantages. The Examiner cannot agree for the reasons set forth below.

> Applicant states (12/11/2006 response, page 6 of 8) --
>
> To the extent that Fan discloses medical devices including a lubricous polymer coating and an antimicrobial material, such as silver and its salts [ ], Fan does not disclose how to make such a coating, and none of Fan's examples disclose a lubricous polymer coating including silver and a water-swellable polymer.

The Examiner cannot agree with applicant's reading of Fan's disclosure. Fan discloses improved lubricious medical devices such as, for example, catheters, guide wires, endotracheal tubes and implants, which incorporate active ingredients such as virucides, antimicrobials (page 3, second and third paragraphs; pages 4-6). Silver and its compounds are exemplified (page 6, lines 14-17), as are a diverse list of active ingredients such as hormones (page 4, line 17) and antimicrobials (page 6, third paragraph). Suitable lubricious polymers are polymers that become substantially more lubricious when wetted with an aqueous liquid than when dried (page 6, last paragraph), and such polymers include water-swellable polymers, which are hydrophilic polymers that absorb sufficient water to render it lubricous in the hydrated state (page 7, lines 1-4). Carboxymethyl cellulose (page 8, lines 2 & 8), polysaccharides (page 7, line 12) are disclosed.

Fan further provides extensive teachings of making the coated medical devices. 0.05 wt% of a binder polymer to promote bonding of the lubricious polymer to the medical device substrate is used in combination with 0.1-20 wt% of the lubricious

polymer in a liquid medium to coat by a process such as dip-coating, spray-coating, knife-coating and roller coating (paragraph bridging pages 8-9; pages 10-12). The coating process is preferably conducted at atmospheric pressure and temperature range of 20-90°C, and residence times for contacting the surface of the substrate to be coated ranges from about 1 second to 30 minutes (page 12, first full paragraph). Dry coating at 30-150°C for preferably 10 minutes to 10 hours is taught (id.).

An active agent such as a silver compound antimicrobial is incorporated into the polymeric outer surface of a medical device by contacting ("imbibing") said surface with a liquid medium having solvency (a liquid that is a solvent or is effective to promote swelling) for the polymeric outer surface of the medical device (page 13, lines 17-26; page 6, lines 14-17). The liquid medium most preferably contains 10-20 wt% of the active ingredient (page 15, lines 4-8). The contacting can be conducted prior to, simultaneous with or after the application of the lubricious polymer. The imbibing process is carried out at atmospheric pressure and temperature range of 20-90°C by dipping, spraying, rolling or otherwise contacting in the liquid medium having solvency for a relatively short period of time such that there is preferably less than 7% change in either the longitudinal or horizontal dimension or shape of the polymeric substrate of the medical device (page 14, lines 10-17).

By following these detailed "how to make" teachings by Fan, it is the Examiner's position that one having ordinary skill in the art would have been able to make and use

Fan's improved lubricious medical devices. Motivation to utilize Burrell's nanocrystalline, atomically disordered antimicrobial silver compounds arises from advantages of improved antimicrobial efficacy due to the atomic disorder. As a result, the ordinary skilled artisan would have been motivated to incorporate the nanocrystalline, antimicrobial, atomically disordered metals of the elected invention, as taught by Burrell et al., into polymers/matrices, the specifics of which are fairly suggested by Fan, who provide the motivation to utilize the claimed lubricious polymers such as carboxymethyl cellulose, as claimed.

In sum, the claimed invention as a whole would have been obvious to the ordinary skilled artisan in this field for the reasons of record and additional reasons stated herein; and the prior art references sufficiently enable one skilled in the art to make the subject matter covered by the claims.

Applicant also argues that "it was surprising to Applicants that the inclusion of the atomically disordered antimicrobial metal component of the coatings adheres well to the substrates and does not interfere with the lubricity properties of the dried coating." In this vein, applicant basically ignores the prior art teaching of Fan, which would have led the ordinary skilled artisan to have expected the same. In Fan's process, the antimicrobial component undergoes an "imbibing" step, which incorporates the antimicrobial substance into the polymeric substrate of the medical device (see above discussion). Since this imbibing step can be carried out before or after the application

of the lubricious polymer, it would have been expected that the atomically disordered antimicrobial metal component of the coatings adheres well and does not interfere with the lubricity properties of the dried coating. Additionally, Burrell et al. teach that atomically disordered antimicrobial metals such as silver may be used as adherent coatings and may also be incorporated into a polymeric matrix (column 10, lines 37-42). Applicant's argument is therefore found unpersuasive.

Applicant further argues that it was also surprising to Applicants that the coatings continue to provide both antimicrobial and anti-inflammatory activity when rehydrated for actual use, and that the initial hydration of the polymer and the metal powder to form the coating does not deactivate the metal powder. The Examiner cannot understand this argument at all. There is no objective evidence that atomically disordered silver or other metals can be "deactivated" by a water-swellable polymers such as carboxymethyl cellulose and polysaccharide. Indeed, Burrell et al. teach incorporation into various polymeric matrices for use in medical devices (column 10, lines 37-42). Further, the very definition of Burrell's atomically disordered feature is that atoms, ions, molecules or clusters of the antimicrobials are released into an alcohol or water based electrolyte on a sustainable basis; and medical devices such as those taught by Burrell et al. and Fan come in contact physiological fluid (i.e. water based electrolyte). Applicant's argument is therefore found unpersuasive.

Lastly with regard to applicant's assertion of "surprising" properties, it must be noted that there is no objective evidence to that effect. Further, evidence of nonobviousness, if any, must be commensurate in scope with that of the claimed subject matter. In re Kulling, 14 USPQ2d 1056, 1058 (Fed. Cir. 1990); In re Lindner, 173 USPQ 356, 358 (CCPA 1972).

For these reasons, applicant's arguments are deemed unpersuasive and this ground of rejection must be maintained.

It is noted that applicant is correct in observing a minor error in the Interview Summary Record that was mailed with the previous Office action. The second box in Part III should have been checked since the interview did not result in an allowance.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

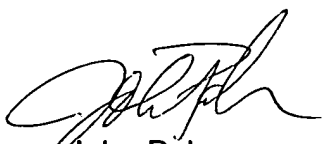
Any inquiry concerning this communication or earlier communications from the Examiner should be directed to JOHN PAK whose telephone number is **(571)272-0620.** The Examiner can normally be reached on Monday to Friday from 8 AM to 4:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's SPE, Johann Richter, can be reached on **(571)272-0646**.

The fax phone number for the organization where this application or proceeding is assigned is **(571)273-8300**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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